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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/080,504

02/22/2002

Olaf Reinhold

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09/18/2008

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/080,504	<b>Applicant(s)</b> REINHOLD ET AL.	
	<b>Examiner</b> KRISTEN C. MATTER	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Action is in response to the amendment filed 8/6/2008. Claims 1, 20, and 21 have been amended, claims 23-84 have been cancelled, and no claims have been added. Currently, claims 1-22 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, has two additional lines (21 and 22) after the period in line 20. It is unclear whether these limitations are to be included in claim 1 or if they are a typographical error. In addition, the limitation "suspension-like" in line 17 is unclear because it is unknown what parts of the attachment must be "suspension-like" to read on the claims. Examiner suggests deleting "-like".

Claims 2-20 are dependent on claim 1 and are therefore rejected for the reasons outlined above with respect to claim 1.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (US 1,105,934) in view of Voges (US 5,894,841) and Gonzalez (US 455,614).

Regarding claim 1, as best understood by the examiner, Stevens discloses a device (fig. 6-7) for delivering an aerosolized compound, comprising: a medicament reservoir (30,31); a housing 1 having an upstream end and a down stream end and comprising an inlet 3 and an outlet between which is formed an airflow path wherein the inlet is located at the upstream end of the housing and facing opposite to the outlet (fig. 7), except for a system comprising an entry port and an element to generate particles of a desired size for physical ejection through apertures from an ejection head.

However, Voges teaches a device (fig. 2) for delivering an aerosolized compound (e.g. nicotine at col .5, line 58), the device comprising: a reservoir (10) that stores the compound; a system comprising an entry port (12) and an element to generate particles of a desired size for physical ejection through one or more apertures (15) from an ejection head (14) of the element, wherein said particles comprise a compound (e.g. nicotine at col.5, line 58), and wherein said system is fluidly connected (11) to a reservoir (10); and a housing (2,3) comprising an inlet (7) and an outlet (5) between which is formed an airflow path (see bold arrows in fig. 2 extending from outside of housing 2,3 through inlet 7 and through outlet 5) and in which at least the ejection head is disposed in the air flow path (i.e. as illustrated in fig.2) downstream of the inlet (7) and upstream from the outlet (5), wherein the housing provides for a substantially unobstructed airflow between the ejection head and the outlet when air traverses the airflow path

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from the inlet to the outlet. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in the Stevens reference to include a system having all the features as discussed above, as suggested and taught by Vogues, for the purpose of providing a thermal droplet ejection system that could issue a predetermined number of discrete droplets of the medication having a uniform size as desired (see abstract). As to the a suspension attachment connecting the system to the housing such that the airflow is substantially unobstructed when between the system and the housing (both Stevens note Fig. 6, 7, element 30 is suspended between the channel via the shape of the ends air is able to flow between the system and housing via the apertures in element (30); Voges teaches a suspension attachment (note Figs. 2, 4, 5; the system is between two ends of the housing (i.e., suspended) and air flows between the system and housing via apertures 7)) therefore Stevens and Voges are readable upon the limitation of a suspension-like attachment.

In addition, the modified Stevens and Voges reference is silent as to an inner surface of the housing proximal to the ejection head and extending to the outlet being contoured to minimize turbulence. Gonzalez, in a device for delivering an aerosolized compound (page 1, col.2, lines 100+), teaches an inner surface of the housing is proximal to the aerosol generation system and extending to the outlet is contoured (A' to a2 to e2 of fig.1). The contouring of the inner surface of the housing of Gonzalez would implicitly cause variations in the flow rate and flow pattern of the aerosol being formed as it passes there through (e.g. smaller diameter portions would cause increased flow rate and more laminar flow whereas increased diameter portions would cause decreased flow rate and relatively more turbulent flow). Therefore, it would have been obvious to further modify the inner surface of the housing proximal to the ejection head in

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the modified Stevens and Voges device to make it contoured because it would have provided a means for controlling the flow rate and flow pattern of the aerosol being formed as taught by Gonzalez.

Regarding claims 2 and 3, Voges teaches that the compound (col. 5, line 58) is a pharmaceutical compound and is stored in the reservoir (10) in a liquid formulation (col. 5, line 58 discloses nicotine dissolved in water).

Regarding claims 4-8, Voges (col. 9, line 53 - col.10, line 21) discloses a variety of suitable drugs for delivery by the device. These drugs include proteins and hormones (e.g. corticosteroids and antidiuretic hormone), and small molecules (e.g. budesonide) as well as other drugs that are fully capable of being gene delivery vehicles; and the reservoir (10) and particle generating system (14,15) in Voges (fig.2) are illustrated as being located within housing (2,3).

Regarding claims 9-14, Voges teaches that the housing (fig. 2) is aerodynamically shaped (e.g. cylindrically shaped thereby providing for easy flow of air there through and around); the reservoir (10) is being detachable (col. 6, lines 37-40); the reservoir (10) and particle generating system (11,12,14,15) is illustrated (e.g. in fig.2) as being integrated into a single unit; the particle generating system is an electronic ejection device (col. 6, lines 45-51 ); the electronic ejection device uses heat (20 and col. 6, lines 26-30) to generate particles ejected from the ejection head; the electronic ejection device includes a piezoelectric component (col. 10, lines 52-54) to generate particles ejected from the ejection head.

Regarding claims 15-17, Voges discloses the desire particle size is one that allows particles to transit to and be deposited in alveoli (col.9, lines 37-47). That is, Voges recognizes that particles having a diameter less than 5 microns are preferred because particles of this size

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range will follow respiratory passages. One of ordinary skill would recognize respiratory passages to include alveoli.

Regarding claim 18, fig. 2 of Voges illustrates substantially unobstructed airflow being substantially laminar prior to exiting the housing outlet (5).

Regarding claim 19, fig. 2 of Voges illustrates substantially unobstructed airflow comprises a substantially homogeneous mixture of ejected compound and air from inlet (7) prior to exiting the housing outlet (5).

Regarding claim 20, Voges discloses the ejection is by digitally controlled electronic ejection (column 11, line 50).

Claims 21 and 22 are substantially equivalent in scope to claim 1 and are included in Stevens as modified by Vogues and Gonzales for the reasons set forth above with respect to claim 1.

### ***Response to Arguments***

Applicant's arguments filed 8/6/08 have been fully considered but they are not persuasive.

In response to applicant's argument that Stevens and Voges fail to teach contours to minimize turbulence, examiner agrees and points out that that is the reason why the references were combined with Gonzales. Gonzales clearly teaches a contoured inner surface of a similar device for aerosolizing a compound (Fig. 1). It is irrelevant that Gonzales does not teach air flow traveling between the system and the housing (or that Gonzales flow travels through a sponge as argued by applicant) because Gonzales was cited merely to show that it is well known to contour

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the inner surface of a device for aerosolizing a compound in order to control air flow rate and pattern of the aerosol as desired by a user. Increasing flow rate with smaller diameter portions would create more laminar flow and larger diameter portions would create more turbulent flow as is well known in air flow dynamics.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771